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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,099	04/07/2004	Simon McEwen	61190(50221)	8281

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	
MAIL DATE	DELIVERY MODE
07/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,099	MCEWEN, SIMON	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *25-28 and 30* is/are withdrawn from consideration.

5)☒ Claim(s) *29* is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment and remarks filed 4/15/08 are acknowledged.

Claims 1-30 are pending.

Election/Restrictions

Newly submitted claim 30 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 30 is drawn to a method of use of a composition of claim 1 for treating arthritis. The elected group, claims 1-24 and 29, are drawn to a composition. The composition has other uses as demonstrated in the reasons for distinctness of Groups I and II in the restriction requirement mailed on 8/3/07.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 30 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The election of claims 1-24 and 29; and mucopolysaccharidases as the enzyme specie in the reply filed on 4/5/07 are again acknowledged.

Claims 25-28 and 30 stand withdrawn.

Claim Rejections - 35 USC § 112

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition defined by claim 29 for the

treatment of rheumatoid arthritis, does not reasonably provide enablement for a composition comprising a mucopolysaccharidase and an immunogen which are present at a dose that provides benefit to an individual in need of treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant argues that the specification teaches how to make the claimed invention, especially for the treatment of RA. Applicant argues that data from a RA mouse model study was blinded and provided data that is statistically meaningful. Applicant argues that the provided data with the mouse model correlates with an autoimmune disease. Applicant argues that Terr does not refute the probative evidence disclosed by Applicant's disclosure.

Responding to Applicant's arguments, the scope of the enablement rejection has been adjusted to correlate to the data related to the RA mouse model data with a composition that is commensurate in scope with the results from said RA mouse model data. That is, the specification teaches a composition (e.g., that of claim 29 or the disclosure by the specification regarding how to make the composition of claim 29 (page 10, paragraphs 2-3)) that showed an improvement in symptoms of mice that serve as a model for human RA. However, the RA mouse model data does not enable the full scope of the claims which are drawn to composition for treating any autoimmune disease with a combination of any enzyme and immunogen.

The data from the RA mouse model is surprising in light of the prior art. As previously noted, Terr asserted that there have been no published research findings regarding the efficacy of EPD in patients undergoing EPD treatment and the efficacy is anecdotal. Studies on symptomatic improvements in adults or children with allergic rhinitis or asthma due to EPD therapy have very small groups and have been of short duration and generally lacked objective measurements of disease actiivty". Furthermore, the treatment of autoimmune diseases is difficult. For example, there are no reported cures for RA. Furthermore, each disease has its own etiology and symptoms such that a pharmaceutical agent that treats RA would not be effective for treating lupus. Thus, this field of treatment of autoimmune diseases is unpredictable. The indicated composition is enabled to the extent that it is supported by the disclosure. The specification fails to guidance for making or using any other composition of claims 1-24 with a reasonable expectation of results.

Claim 29 is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651

/Sandra Saucier/
Primary Examiner, Art Unit 1651